



Australian Government

Medical Services Advisory Committee

Public Summary Document

Application No. 1546 – Abdominoplasty with repair of rectus diastasis (aka rectus divarication) following pregnancy

Applicant: Australian Society of Plastic Surgeons

Date of MSAC consideration: MSAC 77th Meeting, 28-29 November 2019

Context for decision: MSAC makes its advice in accordance with its Terms of Reference, [visit the MSAC website](#)

1. Purpose of application

An application requesting Medicare Benefits Schedule (MBS) listing of abdominoplasty for the repair of rectus diastasis in women who developed symptomatic rectus diastasis following pregnancy was received from the Australian Society of Plastic Surgeons by the Department of Health.

2. MSAC's advice to the Minister

After considering the strength of the available evidence in relation to comparative safety, clinical effectiveness and cost-effectiveness, MSAC did not support public funding of abdominoplasty with repair of rectus diastasis (aka rectus divarication; RD) following pregnancy. MSAC considered that the magnitude of benefit relative to best supportive care (i.e. physiotherapy and/or exercise) was uncertain and as a consequence the incremental cost-effectiveness was also uncertain.

Consumer summary

The Australian Society of Plastic Surgeons applied for public funding through the Medicare Benefits Schedule (MBS) for surgery to fix separation of the abdominal muscles after pregnancy, a condition known as rectus diastasis or rectus divarication (RD). In this surgery (abdominoplasty), extra flesh is removed from the abdomen and the muscles are 'sewn' back together. Letters of support for funding RD were received from consumers.

The application was for funding of abdominoplasty after a woman has been pregnant and has tried to improve her abdominal muscles with exercise, physiotherapy, or weight loss. It is not intended for cosmetic reasons. It is sometimes difficult to tell if RD has happened directly because of pregnancy or some other cause, for example significant weight loss prior to pregnancy.

Consumer summary

This application assumed that RD causes back pain and urinary incontinence, but there is no scientific evidence that it does cause those issues. In addition, the scientific studies that were done to test if surgery is better than other types of care (such as exercise or physiotherapy) were done in a way that means the results could be biased; that is, it might look like surgery is better than it really is. For these reasons, MSAC could not say, based on the evidence provided in the application, that surgery is the best way to treat RD in women who have been pregnant.

MSAC's advice to the Commonwealth Minister for Health

Due to the lack of evidence of clinical benefit, MSAC did not support public funding for surgical repair of RD following pregnancy.

3. Summary of consideration and rationale for MSAC's advice

MSAC noted that this item was removed from the MBS in 2016 during the MBS review of lipectomy items 30165, 30168, 30171, 30174 and 30177, because of concerns of use in women who wanted the procedure for cosmetic reasons.

MSAC noted that there were a high number of adverse events with this surgery, although these may be relatively minor, as well as a small risk of RD recurrence. Therefore, in terms of safety, MSAC considered abdominoplasty as inferior compared to standard care.

MSAC noted very low confidence in the conclusion that surgery is superior to physical therapy in terms of clinical effectiveness. MSAC noted a number of issues with the two studies on which this submission was based:

- For Emanuelsson et al. (2016)
 - inclusion criteria included “wants abdominal wall reconstruction” which may bias results towards surgery
 - the study included some men, and not all women were postpartum but had the procedure for other reasons (e.g. gastric bypass)
 - patients could cross over from physical therapy to surgery if not satisfied, and most did, which would bias towards surgery
 - assessors were not blinded to the allocation of patients to the physical therapy or surgery arms, which could lead to an overestimation of the benefit of the surgical intervention
 - outcomes at 3 months for physical therapy were compared to outcomes at 12 months after surgery; however, by 12 months the outcomes for non-operative treatment might have been the same or better than for surgery at 12 months
 - no between-group differences were reported: the study authors only looked at within-group differences and compared those with general population norms for the SF-36 questionnaire (quality of life measures).
- For Taylor et al. (2018)
 - it was not clear if all participants had rectus diastasis or not, and there was no measurement of the severity of any diastasis
 - the study was unblinded and there was no control group, which is likely to bias in favour of surgery.

In addition, MSAC noted that the Taylor study had outcomes of back pain-related disability and urinary incontinence. MSAC considered this problematic as it is unclear that rectus diastasis actually causes either of these symptoms, even though this seems to be a commonly held belief. MSAC noted there are many types of urinary incontinence, each requiring a specific diagnosis. Some of which e.g. detrusor instability, are treated with medical therapy and would not be ameliorated by repair of the anterior abdominal wall. MSAC noted two papers (Sperstad et al *Br J Sports Med* 2016 and Bo et al. *Neurourol Urodyn* 2017) that both report on a study of 300 consecutive women with first pregnancy, followed until 12 months post-partum, which showed no difference in either symptom by the presence or absence of RD.

MSAC also noted that it is not clear how to differentiate between pregnancy-related RD and non-pregnancy-related RD in women who have been pregnant.

MSAC noted that the incremental cost-effectiveness ratio (ICER) is in the range typically considered to be acceptable at \$40,000 per quality-adjusted life year, and there is a modest financial impact of \$1.4 million per year. These are conditional on the procedure not being used in women who want it for cosmetic purposes (noting that this was the reason the item was removed from the MBS). However, since the clinical evidence is uncertain, the cost-effectiveness is also uncertain.

MSAC noted the pre-MSAC response from the applicant which stated that the removal of this item from the MBS disproportionately affects women, that the size of the treatment population is small, and that the reason no comparator arm was included in the Taylor study is that abdominoplasty is the standard of care in the real-world setting.

MSAC acknowledged that this procedure is being done in the community and also acknowledged the apparent inequity of pregnant women being excluded from MBS funding. However, MSAC also noted that there are risks inherent with surgery and these risks outweigh the claimed benefit.

4. Background

The purpose of Application 1546 is to reinstate MBS funding for abdominoplasty with repair of rectus diastasis in women who developed symptomatic rectus diastasis following pregnancy. In 2016, this patient group was removed from the MBS item 30177 after a review of abdominoplasty in the management of urinary incontinence due to concerns that the surgery was performed for largely cosmetic reasons and had no significant morbidity or mortality benefit.

5. Prerequisites to implementation of any funding advice

Nil, the service would be performed by a specialist surgeon in an accredited hospital.

6. Proposal for public funding

The medical service proposed is the surgical repair of symptomatic rectus diastasis which is over the threshold distance of 3cm and where the patients have a recognised and documented pattern of symptoms – low back pain, daily abdominal discomfort on functional use and/or urinary incontinence. The repair would involve suturing the musculoaponeurotic layer of the abdominal wall and including associated excision of redundant skin and fat and transposition

of the umbilicus (radical abdominoplasty). It would not be performed within 12 months of pregnancy.

The proposed population for abdominoplasty with surgical repair of the rectus diastasis are women with pregnancy-acquired rectus diastasis. Specifically, these women:

- are at least 12 month post-partum;
- have a diastasis of at least 3 cm; and
- have documented evidence of functional symptoms of low back pain and daily abdominal discomfort on functional use in the case notes.

The applicant's proposed MBS item descriptor is summarised in Table 1.

Table 1: Proposed updated wording to existing Item 30176

<p>Item 30176 – Category 3 – Therapeutic Procedures</p> <p>Group T8 – Surgical operations</p> <p>Subgroup 1 – General</p> <p>Lipectomy, radical abdominoplasty (Pitanguy type or similar), with excision of skin and subcutaneous tissue, repair of musculoaponeurotic layer and transposition of umbilicus, not being a service associated with a service to which item 30165, 30168, 30171, 30172, 30177, 30179, 45530, 45564 or 45565 applies, if and where it can be demonstrated that one of the following conditions is present:</p> <p style="padding-left: 40px;">a) the patient has previously had a massive intra-abdominal or pelvic tumour surgically removed; or</p> <p style="padding-left: 40px;">b) anterior abdominal wall defect that is a consequence of pregnancy and the patient must:</p> <p style="padding-left: 80px;">I. not be receiving this service within 12 months after the end of a pregnancy (once in a lifetime);</p> <p style="padding-left: 80px;">II. have a diastasis of at least 3 cm (measured by appropriate pre-procedure diagnostic imaging); and</p> <p style="padding-left: 80px;">III. have documented functional symptoms (in the case notes) of lower back pain, combined with daily pain or discomfort at the site of the diastasis in the abdominal wall during functional use</p> <p>(H)</p> <p>Multiple Operation Rule (Anaes.) (Assist.)</p> <p>MBS Fee: \$985.70 Benefit: 75% = \$739.30</p>

Table 1, p17 of the CA

An alternative item descriptor was proposed during the assessment. The Critique stated that the proposed alternative descriptor in Table 2 would make it easier to monitor usage, as it would separate pregnancy-related treatment from treatment of tumours, as suggested by PASC. It would also remove this service from the lipectomy item numbers.

Table 2: Proposed alternative MBS item descriptor

Category 3017X – Category 3 – Therapeutic Procedures
Group T8 – surgical operations Subgroup 1 – general
Lipectomy, radical abdominoplasty (Pitanguy type or similar), with excision of skin and subcutaneous tissue, repair of musculoaponeurotic layer and transposition of umbilicus, not being a service associated with a service to which item 30165, 30168, 30171, 30172, 30176, 30177, 30179, 45530, 45564 or 45565 applies, and where it can be demonstrated, by pre-procedure imaging, that the patient has an abdominal wall defect as a consequence of pregnancy and must: a) not be receiving this service (once per lifetime) within 12 months after the end of a pregnancy; b) have a diastasis of at least 3cm (measured by appropriate diagnostic imaging); and c) have documented functional symptoms (in the case notes) of lower back pain, combined with daily pain or discomfort at the site of the diastasis in the abdominal wall during functional use (H) Multiple Operation Rule (Anaes.) (Assist.)
Fee: \$985.70 Benefit: 75% = \$739.30

Source: Table 12, p37 of the CA

Four societies were contacted in the targeted consultation. The National Association of Specialist Obstetricians & Gynaecologists was the only organisation that replied, and they supported the application.

One plastic surgeon also expressed support for the application, but that individual is also the contact person named on the application (on behalf of the Australian Society of Plastic Surgeons).

More than 10 additional survey responses were received, mostly from women (some received surgery or would like access to surgery) and that all were supportive. They described improvements in quality of life after the procedure, and cited cost as a major barrier to accessing the service.

7. Proposed intervention's place in clinical management

Currently, there are no MBS-funded treatment options for patients with post-pregnancy rectus diastasis who are nonresponsive to conservative treatments (such as physiotherapy, exercise, lifestyle changes and painkillers). In current clinical practice, these patients can be offered best supportive care to manage symptoms, with or without these conservative treatments (Figure 1).

It is claimed that if abdominoplasty with surgical repair of the rectus diastasis was reinstated for this patient group, patients who fail to respond to conservative treatment would be given the option to either manage their functional and pain symptoms with best supportive care or undergo curative surgery with abdominoplasty (Figure 2).

The application noted that whilst physiotherapy and/or exercise is commonly used to treat rectus diastasis, it is used much earlier in treatment than abdominoplasty. The applicant stated that patients generally only consider surgery after they have exhausted all other treatment options (i.e. patients have already tried and failed multiple exercise/physiotherapy programs).

The Critique stated that the current clinical practice guidelines were considered appropriate. However, the Critique stated that the proposed clinical algorithm was missing initial surgery

consultation and any further consultation (MBS codes 104 and 105, respectively). This consultation would assess the eligibility for use of the proposed MBS item.

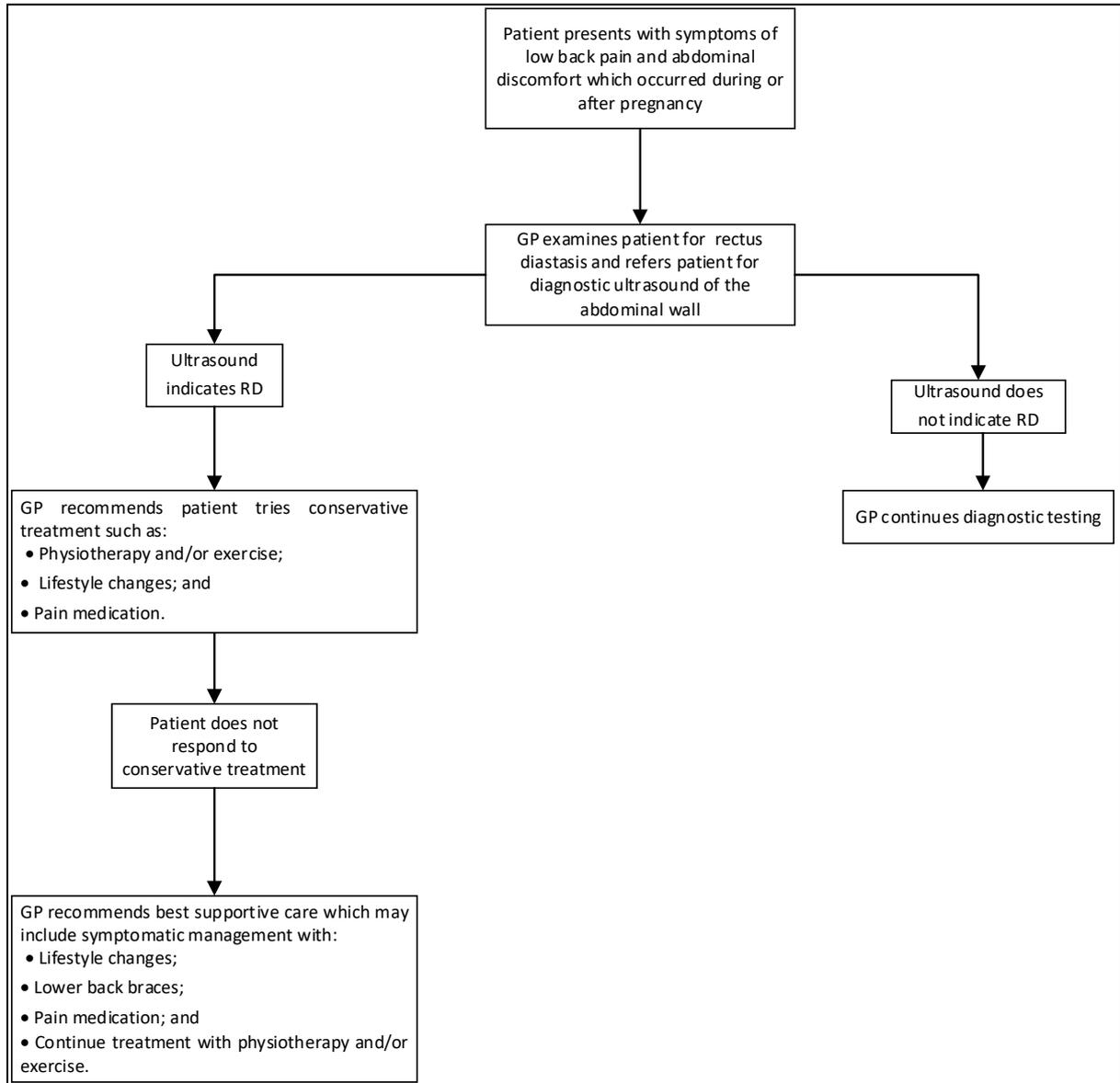


Figure 1: Current available treatment options for patients with pregnancy-acquired rectus diastasis

GP = general practitioner; RD = rectus diastasis

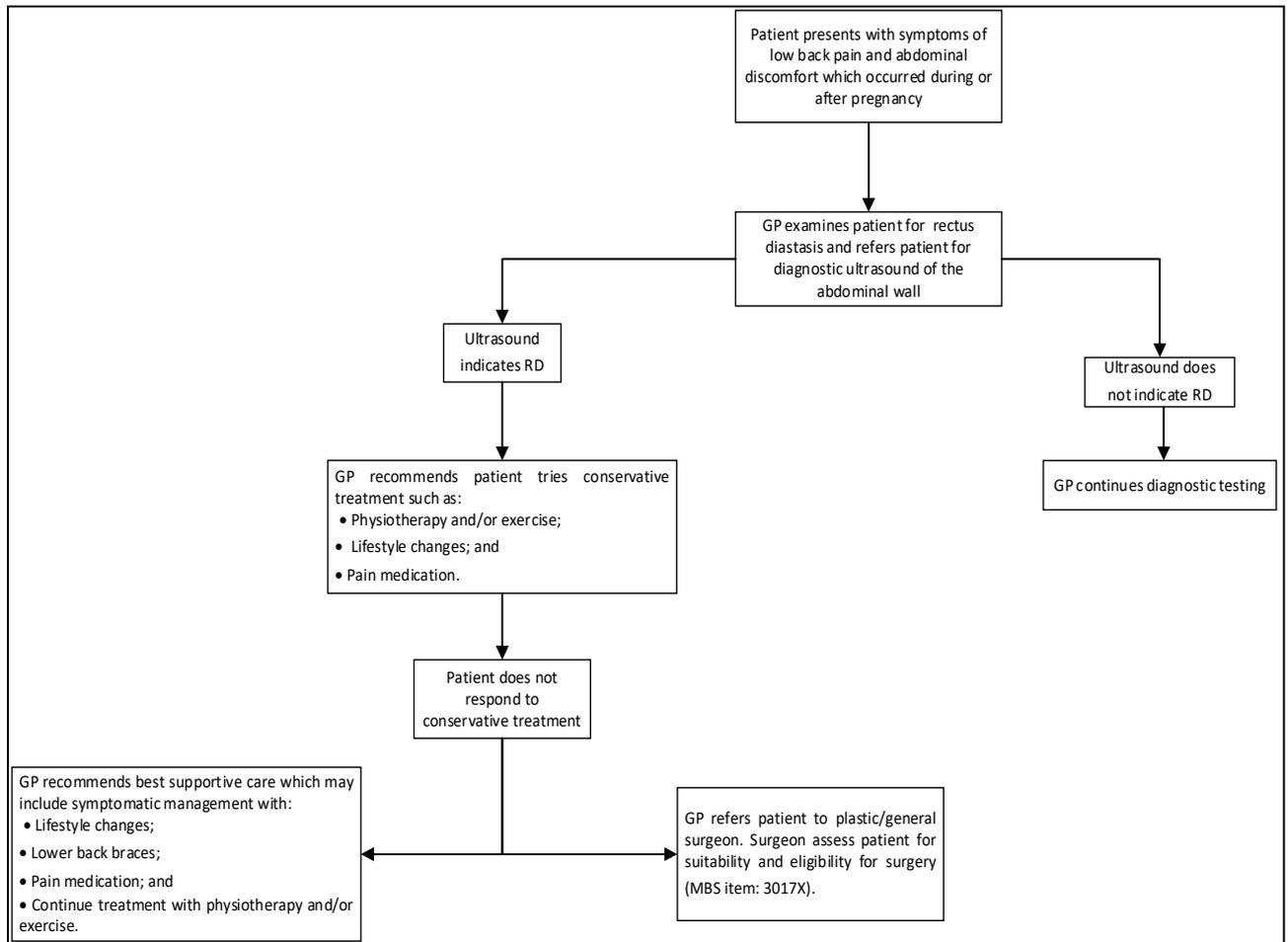


Figure 2: Available treatment options for patients with pregnancy-acquired rectus diastasis if this patient group is reinstated

GP = general practitioner; MBS = Medicare Benefits Schedule, RD = rectus diastasis

8. Comparator

Best supportive care was nominated as the main comparator. Best supportive care includes symptomatic treatment with painkillers, lower back braces and lifestyle changes. The patient's doctor may also recommend that the patient continue with their physiotherapy and/or exercise program to manage symptoms.

9. Comparative safety

Two studies were identified. The pivotal randomised controlled trial (RCT) by Emanuelsson *et al.* (2016) (N = 86), provided direct evidence of the comparative efficacy of abdominoplasty with surgical repair of the rectus diastasis relative to a three months exercise/physiotherapy program (i.e. best supportive care). The Australian prospective cohort study (N = 214) by Taylor *et al.* (2018) [3] provided supportive evidence that abdominoplasty is effective at reducing post-partum women's symptoms of urinary incontinence and back pain.

Data from the Emanuelsson trial suggested that abdominoplasty had inferior comparative safety to best supportive care (i.e. physiotherapy and/or exercise). In the surgical group, 22/57 patients (39%) experienced at least one complication, compared to no patient in the exercise group. Specifically, the incidence of wound infection, seroma or haematoma and

recurrence of diastasis was greater in the surgical arm when compared to the exercise group. During the trial's 12-month follow-up, one (1.75%) patient (N=57) in the surgery group experienced recurrence.

10. Comparative effectiveness

Clinical claim

Based on the evidence profile (summarised in Table 3), it is suggested that, relative to best supportive care (i.e. physiotherapy and/or exercise), abdominoplasty has superior efficacy. However, the application stated that the magnitude of benefit is uncertain as:

- Both studies had a high risk of bias:
 - In the Emanuelsson trial, abdominoplasty patients (i.e. mesh and Quill) had 12 months of follow-up, whilst exercise patients only had three months of follow-up. While there was a difference at three months between the groups, patients in the exercise group did not have the full 12 months to experience improvement and if improvement was slower in the exercise group this could favour surgery;
 - Given the nature of the intervention (i.e. abdominoplasty vs. a three-month exercise program), neither patients nor assessors were blinded to treatment allocation in the Emanuelsson trial. This may have introduced response bias into the trial as only patients who desired surgery were enrolled and most of the outcomes relied on self-reporting; and
 - The Australian cohort study had a pre- and post-research design without a valid control group and was thus vulnerable to producing spurious results.
- Exercise patients in the Emanuelsson trial also experienced statistically significant and clinically meaningful improvements in health-related quality of life and improved muscle strength at three months follow-up; and
- The data from the Australian cohort study suggested post-partum women who underwent abdominoplasty experienced statistically significant improvements in back pain (mean difference (MD) = -9.32 (95% confidence interval (CI): -10.40 to -8.40) and uncategorised urinary incontinence (MD = -4.62 (95% CI: -5.43 to -3.81) at six months follow-up. However, these effects were smaller than the minimal clinically important difference (MCID) at six months follow-up.

Pre-ESC response

The applicant provided feedback for the contracted assessment (CA) nominated minimally clinical important differences (MCIDs):

- For assessing low back pain, the CA used the Oswestry Disability Index (ODI) MCID of 9.5, which was referenced from a study about an eight week exercise program conducted in Italy. The applicant stated that the reported MCID of 9.5 was in fact a summary finding with the actual research stating on p127 “The optimal cut-off points estimated on the basis of ROC analysis were 9.0–9.5 for ODI and 2.5 for RMDQ, both of which are in line with those published by other authors.” So on the basis of the full, reported findings, the Taylor result would in fact make the cut-off.
- For assessing urinary incontinence, the CA used the International Consultation on Incontinence Questionnaire (ICIQ) from Sirls et al. (2015). The applicant stated ‘Triangulation analysis supports a MID at -5 at 12 months and -4 at 24 months.’ Taylor’s findings were -4.59 at 6 weeks; -4.62 at 6 months, so comparing them with an expected finding at 12 months is invalid.

Table 3: Clinical benefits of abdominoplasty, relative to exercise, and as measured by the critical and important patient-relevant outcomes in the key studies

Outcomes (units) Follow-up	Participants	Quality of evidence (GRADE)	Mean change from baseline. Mean difference (95%CI)	Relative effect (95%CI). Surgery vs. standard care	Comments
Back pain –measured by the ODI at pre-op, 6 weeks and 6 months post-op	K =1, N = 214 Prospective cohort study of Australian women (pre and post study design)	⊕⊕⊖⊖	MD at 6 weeks: -6.93 (-8.16; -5.70) MD at 6 months: -9.32 (-10.40; -8.24)		A negative mean difference relates to an improvement in back pain. However, these changes were not clinically significant using the proposed MCID of a reduction of 9.5 points. Further, there was uncertainty due the study's research design (i.e. no comparator group).
Urinary incontinence symptoms – measured by the ICIQ at pre-op, 6 weeks and 6 months post-op	K = 1, N = 214 Prospective cohort study of Australian women (pre and post study design)	⊕⊕⊖⊖	MD at 6 weeks: -4.59 (-5.40; -3.78) MD at 6 months: -4.62 (-5.43; -3.81)		A negative mean difference relates to a reduction of uncategorised urinary incontinence signs. Abdominoplasty significantly reduced patients' urinary incontinence symptoms at six weeks and six months follow-up, however these results were not clinically significant using the proposed MCID of 5 points. Further, there was uncertainty due the study's research design (i.e. no comparator group) as the effect was based on change from baseline.
Health-related quality of life (as measured by the SF-36)	K=1, N = 86 Emanuelsson's trial	⊕⊕⊖⊖	Abdominoplasty patients (mesh + Quill) at 12 months: PF: MD = 10.38 (6.64; 14.11) * RP: MD = 21.80 (12.29; 31.32) * BP: MD = 15.76 (10.34; 21.18) * GH: MD = 9.58 (4.86; 14.29) * VT: MD = 15.90 (9.31; 22.49) * SF: MD = 17.26 (8.69; 25.82) * RE: MD = 13.18 (3.43; 22.94) * MH: MD = 5.74 (0.35; 11.12) Exercise patients at 3 months: PF: MD = 4.57 (0.66; 8.48) RP: MD = 18.70 (6.56; 30.83) * BP: MD = 7.03 (0.32; 13.74) GH: MD = -3.94(-10.28; 2.41)	Surgery (mesh + Quill) (12 M follow-up) vs. Exercise (3 M follow-up): PF: MD = 5.95 (0.16; 11.75) RP: MD = 3.89 (-11.66; 19.44) BP: MD = 8.87 (0.04; 17.70) * GH: MD = 13.77 (5.90; 21.65) * VT: MD = 8.24 (-1.92; 18.41) * SF: MD = 12.50 (-0.91; 25.91) * RE: MD = 8.24 (-1.92; 18.41) * MH: MD = 2.61 (-5.50; 10.71)	Compared to patients allocated to exercise, abdominoplasty patients experienced both clinically and statistically significant improvements in the SF-36 domains measuring "General Health" and "Bodily Pain" at 12 follow-up. However, given the difference in follow-up time between exercise and surgical groups (3 months vs. 12 months), these results should be interpreted with caution.

Outcomes (units) Follow-up	Participants	Quality of evidence (GRADE)	Mean change from baseline. Mean difference (95%CI)	Relative effect (95%CI). Surgery vs. standard care	Comments
			VT: MD = 7.88 (1.24; 14.52) SF: MD = 5.30 (-3.93; 14.53) RE: MD =5.40 (-8.41; 19.20) MH: MD = 3.16 (-1.66; 7.99)		
Proportion of patients reporting they have abdominal wall pain right now that is not easily ignored (VHQP)	K=1, N = 86 Emanuelsson's trial	⊕⊕⊕⊖	Abdominoplasty patients (mesh + Quill) -at 3 months follow-up: OR =0.97 (0.39, 2.42) -at 12 months follow-up OR = 0.31 (0.11, 0.92) Exercise patients at 3 months follow-up: OR = 2.18 (0.51, 9.33)	Not comparable	Abdominoplasty patients reported a significant reduction in pain at 12 months follow-up but not at three months follow-up, there was no indication as to what exercise was advised post operatively. Exercise patients were marginally more likely to report pain at three months follow-up than at baseline. However, given the limited data available and difference in follow-up time, it was not possible to compare treatment groups.
Improvements in abdominal wall strength (VAS).	K=1, N = 86 Emanuelsson's trial	⊕⊕⊕⊖	At 3 months follow-up treatment groups Mesh (i.e. surgery) : mean = 6.9 (range: 0 - 10) Quill: (i.e. surgery) mean = 6.9 (range: 0 - 10) Exercise: median =3 (SD 2.76) At 12 months follow-up (surgical groups only) Mesh: median = 8 (SD: 10) Quill: median = 7 (SD: 2.26)	Compared to exercise patients at 3 months follow-up, both surgical groups (mesh and Quill) reported significantly greater improvements in abdominal strength at 12 months follow-up (p < 0.05).	Abdominoplasty patients (in mesh and Quill groups) were more likely to report perceived improvements in abdominal wall strength at 12 months follow-up, compared to exercise patients at three months follow-up. However, given the limited data available and difference in follow-up time, it was difficult to compare treatment groups.

BP = Bodily Pain; CI = confidence interval; GH = General Health; ICIQ = International Consultation on Incontinence Questionnaire; M = months, MCID = minimally clinically important difference; MD = mean difference, MH = Mental Health; ODI = Oswestry Disability Index; OR = odds ratio; PF = Physical Function; RE = Emotional Role Functioning; RP = Physical Role Functioning; SD = standard deviation; SF = Social Functioning; VAS = visual analogue scale, VHPQ = Ventral Hernia Pain Questionnaire; VT =Vitality, **Bold** = statistically significant change from baseline (p < 0.05); * = clinically significant (i.e. above the proposed MCID)

⊕⊕⊕⊕ **High quality:** We are very confident that the true effect lies close to that of the estimate of effect.

⊕⊕⊕⊖ **Moderate quality:** We are moderately confident in the effect estimate: The true effect is likely to be close to the estimate of the effect, but there is a possibility that it is substantially different.

⊕⊕⊖⊖ **Low quality:** Our confidence in the effect estimate is limited: The true effect may be substantially different from the estimate of the effect.

⊕⊖⊖⊖ **Very low quality:** We have very little confidence in the effect estimate: The true effect is likely to be substantially different.

11. Economic evaluation

A cost-utility analysis was undertaken, which was based on 12 months of trial data from the Emanuelsson trial and was then extrapolated to five years (see Table 4).

Table 4: Summary of the economic evaluation

Perspective	Australian health system
Comparator	Best supportive care
Type of economic evaluation	Cost-effectiveness evaluation.
Sources of evidence	Emanuelsson trial
Time horizon	Trial based evaluation: 12 months follow-up in the surgical arms and 3 months of follow-up in the exercise arm (i.e. best supportive care) Modelled evaluation: 5 years
Outcomes	QALYS
Methods used to generate results	Cohort expected value analysis, Markov model
Health states	Abdominoplasty arm: State 1: Alive without recurrent rectus diastasis (i.e. surgery was successful) State 2: Alive with recurrent rectus diastasis (i.e. surgery failed → patient receives best supportive care) State 3: Dead Best supportive care arm: State 1: Alive State 2: Dead
Cycle length	3 monthly cycles (i.e. 90 days)
Discount rate	5%
Software package used	Treeage Pro

QALY = quality-adjusted life year

There are several key structural assumptions in the economic model:

- Rectus diastasis and treatment choice (i.e. abdominoplasty best or best supportive care) impacts only the patient's quality of life but has no impact on the patient's risk of mortality or morbidity;
- Patients only consider abdominoplasty after completing their families;
- Patients have a 1.75% risk of experiencing recurrence of the rectus diastasis in the first year after undergoing abdominoplasty and then no risk after that; and
- Patients who experienced recurrence will not be eligible to undergo MBS funded abdominoplasty and instead will receive best supportive care.

The economic model incorporated health-related quality life data from the Emanuelsson trial and Australian healthcare costs to estimate the cost effectiveness of abdominoplasty compared to best supportive care. The results are shown below in Table 5.

Table 5: Stepped economic evaluation (5% discount per annum applied)

Step and component	Abdominoplasty	Usual Care	Increment
Step 1: trial-based economic evaluation (12 months' time horizon)			
Cost	\$12,195	\$311	\$11,884
LYs	1.00	1.00	0
QALYs	0.59	0.57	0.02
Incremental cost per QALY gained			\$483,676
Step2: modelled economic evaluation extrapolated after 12 months to 5 years			
Cost	\$12,195	\$311	\$11,884
LYs	4.45	4.45	0
QALYs	2.95	2.66	0.30
Incremental cost per QALY gained			\$39,942

Source: Base Case.trex

LY = life years; QALY = quality adjusted life years

The application stated that the incremental cost-effectiveness ratio (ICER) was most sensitive to changes in the time horizon, the utility weights applied (i.e. Australian utility weights vs. United Kingdom utility weights), not allowing abdominoplasty patients utility to increase after three months and the cost of surgery. The model was relatively insensitive to changes in the recurrence rate, cost of best supportive care and discounting.

The model substantially underestimated the cost of best supportive care. The model used five items of physiotherapy based on chronic disease Medicare items. However the pivotal trial evidence was for three times a week for 12 weeks or 36 episodes of care. Follow-up care was not included in either arm.

12. Financial/budgetary impacts

An incidence-based epidemiological approach was used to estimate the financial implications of reinstating abdominoplasty for patients with post-pregnancy rectus diastasis. The method used to calculate the eligible population was based on the average number of births per confinement adjusted by the fertility rate. This estimate was then adjusted using data from Sperstad *et al.* (2016) [4], which reported on the number of primiparous women with rectus diastasis of two finger widths (approximately 3 cm) at 12 months post-partum and who had lumbopelvic pain. Uptake was based the historic rate of uptake of MBS item 30177 amongst post-partum women.

The financial implications to the MBS resulting from the proposed listing of abdominoplasty for women with pregnancy-acquired rectus diastasis are summarised in Table 6.

Table 6: Total costs to the MBS associated with listing abdominoplasty for women with pregnancy-acquired rectus diastasis

-	2020	2021	2022	2023	2024
Eligible patients	21,281	21,706	22,106	22,477	22,819
Uptake (5.35%)	1,139	1,161	1,183	1,203	1,221
Abdominoplasty: MBS	item 3017X				
Number of services	1,139	1,161	1,183	1,203	1,221
Sub-total cost (75% fee)	\$842,034	\$858,298	\$874,562	\$889,348	\$902,655
Co-administered services:	MBS Items 104,	105, 20803,	and 23083^a		
Number of services	9,795	9,985	10,174	10,346	10,501
Sub-total cost	\$523,708	\$533,824	\$543,939	\$553,135	\$561,412
Total services	10,934	11,146	11,357	11,549	11,722
Total cost	\$1,365,742	\$1,392,122	\$1,418,502	\$1,442,483	\$1,464,066

Source: Section E spreadsheet

MBS = Medicare Benefits Schedule

^a For MBS items incurred outside of hospital the 85% MBS rebate was applied (MBS item 104 and 105). For MBS items incurred in hospital the 75% was applied (MBS items 2083 and 2383).

The total cost to the MBS was estimated to be \$1.4 million in 2020, increasing to \$1.5 million in 2024. The proposed service was not expected to have broader impacts on the MBS. The Critique stated that the uptake rate and financial estimates are likely to be reasonably accurate.

13. Key issues from ESC for MSAC

ESC key issue	ESC advice to MSAC
Efficacy of post-partum abdominoplasty	Clinical evidence suggests superior efficacy of abdominoplasty vs best supportive care (BSC; i.e. exercise/physiotherapy) based on health-related quality of life, but magnitude of benefit is uncertain because of high-to-serious risk of bias in included studies.
Safety of post-partum abdominoplasty	Clinical evidence suggests inferior safety of abdominoplasty vs BSC.
MBS item descriptor	Recommend separate new item descriptor 3017X. Suggest revised wording.
Cost implications and possible offsets	Number of predicted services per annum only small (~1,139) Modest additional costs to Medicare
Lack of follow-up for BSC group	In the exercise arm of the pivotal trial, most BSC patients went on to receive surgery following conclusion of the exercise program as they were not satisfied with the result. Hence there is no 1-year follow-up data for that group.
Modelling	Most of the issues relating to the model favour BSC.

ESC discussion

The applicant proposed either adding criteria about pregnancy-related diastasis to Item 30177 or creating a new item number. PASC and the Critique recommended making a new item number. ESC noted that, because this is an in-hospital procedure, a separate item number would allow data to be collected about how it is charged, which would be useful information for MSAC.

ESC noted that some minor changes to wording in the MBS item descriptor are required. Imaging cannot detect whether the abdominal wall defect is a consequence of pregnancy.

Therefore, the preferred wording is, ‘... and where it can be demonstrated by pre-procedure imaging that the patient has an abdominal wall defect, and which is a consequence of pregnancy, ...’

ESC noted that there are many forms of urinary incontinence, and determining which form a patient has requires clinical investigation and diagnosis by a specialist and then appropriate treatment according to sub-type. If urinary incontinence were to be mentioned in the item descriptor, there may be an assumption that a woman with any form urinary incontinence may improve with diastasis surgery. Therefore, ESC agreed that the descriptor should not mention urinary incontinence as an indication for abdominoplasty.

ESC confirmed that this procedure should be limited to once per lifetime only and not for recurrence.

ESC noted that the item is proposed for women at least 12 months post-partum. There was not anticipated to be a deleterious effect on future pregnancies in women who have had abdominoplasty. However, no data were presented reporting surgical failure during, or after, subsequent pregnancies.

ESC noted data presented from two recent studies showing that improvements in back pain and urinary incontinence following abdominoplasty were below the proposed threshold for clinical significance at 6 months follow-up.

ESC noted that only estimated surgical costs were used in the model because information was not available about what surgeons charge. ESC requested that the Department provide the data if it is available. *Following the ESC meeting, the Department advised that the average fee charged for MBS item 30177, a comparable item with a different population, is approximately \$5200 while the schedule fee for the item is \$1001.45.*

ESC noted that patients will have to continue with some kind of exercise regimen so there would be ongoing costs for best supportive care (BSC). ESC noted that the model underestimated the cost of BSC because insufficient follow-up costs after surgery were factored into the model.

ESC noted that there were some translation issues – compliance to the exercise program is lower in a real-world setting and the trial had no obese patients, who are more likely to lose weight in the early stages.

ESC noted that at the end of the trial, most people in the BSC arm who were offered surgery took it up, which shows that BSC is not an ideal treatment. This cross-over to the alternate treatment meant that there was no 1-year follow-up for that group.

Overall, ESC considered that most assumptions in the economic model favour BSC. The model favours BSC as:

- Five sessions of physiotherapy rather than the 36 sessions in the trial. Only supplying five sessions would affect both costs and effectiveness.
- Effectiveness would be reduced in real world setting as compliance would be poorer.
- No ongoing costs for back pain or other complications of abdominal diastasis were included in the model. This could include medications for pain and depression and primary care.

The model favours surgery as:

- No follow up treatment was given after surgery; it is assumed that rehabilitation including physiotherapy and exercise would be required after surgery. This favours surgery in the model.

ESC noted the consumer consultation comments indicate that the high cost is currently a disadvantage for consumers who may be unable to afford this procedure in the absence of MBS reimbursement. ESC considered that if listed on the MBS that out-of-pocket costs may impact on uptake of this procedure.

ESC noted that it is incongruous that abdominoplasty is funded following severe weight loss and for rectus diastasis due to large intra-abdominal or pelvic tumours, but not after pregnancy-acquired rectus diastasis.

14. Other significant factors

Nil.

15. Applicant's comments on MSAC's Public Summary Document

The Australian Society of Plastic Surgeons (ASPS) recognise that the MSAC process has rigour but feel that the evaluation of the value of abdominoplasty for repair of rectus diastasis in women with significant back pain and other symptoms has not been adequate. In particular it has not taken proper regard of the fact that abdominoplasty was the standard of care in Australia for the last 30 years, in contrast to most procedures proposed to MSAC, which are novel procedures. The withdrawal of this service in 2016 has disproportionately affected women with back pain compared to men as it is a treatment for a complication of pregnancy (which only occurs in women).

ASPS agree that the procedure can be used for cosmetic purposes, however, the delineation of eligibility was designed to remove access for the group seeking surgery for cosmetic purposes. There is a parallel here to rhinoplasty where it is acknowledged that the procedure can be reconstructive or cosmetic and a metric has been introduced to appropriately award item numbers. MSAC's response in this circumstance should have been to seek to understand where that threshold is rather than argue about whether there is a threshold. The presence of 30176 in the schedule acknowledges that there is a threshold.

With respect to lack of public support, ASPS would point out that the application had been accompanied by letters of support from General Surgeons Australia, Centre of Perinatal Excellence and the National Physiotherapy Association.

In terms of the MSAC technical evaluation of the evidence supporting the procedure, the MID thresholds and time horizons used in the health economic analysis were not appropriate for this particular procedure which created bias against the procedure. MSAC's threshold of only really considering prospective randomised trials is not consistent with what is available in most surgical fields, especially for a long-established procedure. The focus of ESC on "physiotherapy", which is not a proven treatment for this pathology, was also not appropriate. There were no studies evaluated or presented to support the effectiveness of physiotherapy for rectus diastasis associated with back pain. MSAC's argument that this "treatment", which has no proven efficacy, has less cost and less morbidity therefore seems irrelevant. Leaving patients with funded access only to this (non)treatment seems fundamentally unscientific not backed by evidence. It remains the belief of ASPS that the decision for withdrawal of the funding for abdominoplasty for this indication in 2016 was based on cost rather than the best

interests of patients. This recent decision by MSAC is similarly disappointing for this cohort of women in need.

16. Further information on MSAC

MSAC Terms of Reference and other information are available on the MSAC Website:
[visit the MSAC website](#)